REMARKS

The remainder of this Reply is set forth under subheadings for the convenience of the Examiner.

Specification Amendment

In response to the Examiner's objection to the written disclosure, Applicant amended the specification to recite the elements of Claims 1, 3, 4 and 10-12. Applicant notes that it is now well accepted that a satisfactory description may be in the claims or any other portion of the originally filed specification. See *In re Koller*, 613 F.2d 819, 204 USPQ 702 (CCPA 1980) (original claims constitute their own description); accord *In re Gardner*, 475 F.2d 1389, 177 USPQ 396 (CCPA 1973); accord *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976). See also M.P.E.P. §2163.I.

This amendment introduces no new matter.

Rejection of Claims 1-6, 10-14 and 28 Under 35 U.S.C. §102(b) over U.S. 4,820,305

The Examiner maintained his rejection of the pending claims over U.S. 4,820,305 (Harms *et al.*). The Examiner stated that FIG. 1 and FIG. 6 of Harms *et al.* show an intervertebral implant formed as a unitary body; the body having a banana-shape and a first continuous radius of curvature less than a second continuous radius of curvature. The Examiner also stated that the body of the device of Harms *et al.* has rhombus-shaped openings that are evenly spaced about the circumference of the device and that the interlinking mesh forms a "serpentine arrangement." The Examiner also stated in the Response to Argument section of the instant Office Action, that he interprets the term "unitary," as it appears in Applicant's Claim 1, as consisting of "multiple things working together as a unit," rather than as consisting of a single piece.

The word "unitary," as employed in Applicant's specification, refers only to embodiments of the intervertebral prosthesis that are a single piece. For example, FIG. 2 depicts one embodiment of a spinal implant of the invention. As can be seen from FIG. 2, the spinal implant is a single piece. Page 6, lines 7-9 of the specification describes the embodiment of FIG. 2 as follows:

> FIG. 2 shows the implant device of the invention, designated generally as 15. In the preferred embodiment illustrated, the unitary body 15 is a cage configured and sized to be inserted between adjacent vertebrae in a single step implantation procedure.

Similarly, page 7, lines 3 and 4, makes reference to the embodiment in FIG. 2 as a unitary cage:

> The unitary cage 15 can be placed from an anterior position (anterior interbody fusion or ALIF), or posteriorly (posterior lumbar interbody fusion or PLIF, tranforaminal interbody fusion or TLIF).

There is no reference to any embodiment of an intervertebral prosthesis in the specification that includes more than a single piece as "unitary."

Applicant has explicitly stated in the specification that the invention is directed to an improved "unitary cage" and contrasted unitary construction with prior art embodiments that included a plurality of elements. For example, as stated at page 6, lines 3-6:

> Typically a pair of elements were implanted. The elements themselves were sometimes cylindrical or tubular bodies, solid plugs or cage designs, to mention a few. The present invention is directed to an improved unitary cage and method for its installation.

Further, Applicant has explicitly described the advantages of their claimed unitary intervertebral prosthesis relative to systems that employ a plurality of components. Specifically, as stated at page 9, lines 14 through 17:

> An invention has been provided with several advantages. The unitary banana-shaped cage of the invention is easier and safer to place within the prepared disc space and is mechanically more stable than the previous two component systems currently in use.

Applicants are entitled to employ terminology that most suitably describes their invention, and may employ drawings to facilitate clarity in their description. Item 15 of the figures plainly shows an embodiment of Applicants' claimed intervertebral prosthesis that is of a single piece. Applicants have characterized that embodiment as "unitary." Moreover,

Applicants have specifically contrasted their "unitary" intervertebral prosthesis with prior art intervertebral prostheses that are of more than a single component.

Applicant's claimed unitary intervertebral prosthesis is not anticipated by the intervertebral implant described by Harms *et al.* There is no disclosure or suggestion in Harms *et al.* of an intervertebral prosthesis that is unitary, as that term is employed by Applicant. Therefore, Applicant's claimed unitary intervertebral prosthesis meets the requirements of 35 U.S.C. §102(b) in view of Harms *et al.*

Reconsideration and withdrawal of the rejection are respectfully requested.

Rejection of Claims Under 35 U.S.C. §103

Claims 15-27 stand rejected under 35 U.S.C. §103(a) as being obvious variously in view of Harms *et al.*, Dove *et al.*, , U.S. 6,302,914 (Michelson), U.S. 5,062,850 (McMillan *et al.*), U.S. 6,245,108 (Biscup), U.S. 6,231,615 (Preissman) and U.S. 6,302,914 (McKay), either separately or in some combination. Regarding Claims 15-20, the Examiner stated that it would have been obvious to use alternative materials as taught by Dove *et al.* for the implant of Harms *et al.* As applied to Claims 24-26, the Examiner stated that it would have been obvious to use an implant with a width falling within the range of 24-28 mm, a height of about 10-16 mm and a length of about 10 mm, as taught by Michelson for the implant of Harms *et al.* With regard to Claim 21, the Examiner stated that it would have been obvious to use polyglycolic acid as the implant material as taught by MacMillan *et al.* for the vertebral implant of Harms *et al.* as modified by Dove *et al.* such that it degrades slowly to provide space for bone ingrowth. Concerning Claims 19 and 22, the Examiner stated that one skilled in the art would have considered it obvious to use the polymethylmethacrylate as the implant material as taught by Biscup for the vertebral implant of Harms *et al.* such that it is accepted by the patient's body and does not adversely cause irritation. The Examiner further stated that, regarding Claims 19, 22 and 23, it would be obvious to inject polymethylmethacrylate with an antibiotic as taught by Preissman with the vertebral implant of Harms *et al.* such that it enhances the treatment given to the patient to reduce infection and provides an efficient way to deliver a cement and antibiotic to a treatment site. With respect to Claim 27, the Examiner stated that it would have been obvious to use a thickness for the arc of the implant of "about 1.5 mm" as taught by McKay for the

implant of Harms *et al.* as modified by Michelson such that it provides a durable support for the vertebrae that can withstand compressible loads.

None of the cited references, taken separately or in combination, remedy the deficiencies of Harms *et al.* as applied to independent Claim 1, as amended. Specifically, none of the references, taken separately or in combination, disclose or suggest an intervertebral prosthesis that includes a banana-shaped unitary body defining openings that form a serpentine arrangement of an interlinking mesh, as in Applicant's claimed invention of amended Claim 1. Therefore, Applicant's invention is not obvious in view of the cited references, taken either separately or in combination, and meets the requirements of 35 U.S.C. §103(a).

Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

HAMILTON, BROOK, SMITH & REYNOLDS, P.C.

By Alexander Akhiezer

Alexander Akhiezer
Registration No. 54,617
Telephone: (978) 341-0036
Facsimile: (978) 341-0136

Concord, MA 01742-9133
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